SEP 2 3 2005

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Sistema de Implante Nacional, Ltda Av. Paes de Barros, 485 Mooca Sao Paulo - SP CEP: 03115-020 Brazil Telephone +55 11 2169-3000 FAX +55 11 2169-3025
Official Contact:	Wladimir Estanquiere
Representative/Consultant:	Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone (858) 792-1235 FAX (858) 792-1236

DEVICE NAME

Classification Name:	Implant, Dental, Root Form (DZE) ; Abutment, Implant, Dental, Endosseous (NHA)
Trade/Proprietary Name:	Sistema de Implante Nacional (S. I. N.) Dental Implant System
Common Name:	Endosseous Dental Implant and Abutment

ESTABLISHMENT REGISTRATION NUMBER

The Establishment Registration number for Sistema de Implante Nacional, Ltda is 3004201263. The Owner/Operator number is 9059509.

DEVICE CLASSIFICATION

FDA has classified endosseous dental implants as Class II devices.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards applicable to endosseous dental implants have been established by FDA. However, CP titanium used to manufacture Systema de Implante Nacional dental implants meet the chemical and mechanical requirements of ASTM F 67 and ISO 5832-2.

PACKAGING/LABELING/PRODUCT INFORMATION

Sistema de Implante Nacional Dental Implants will be packaged in a radiation sterilizable package consisting of a primary container, with implant and auxiliary parts, sealed with a peel-off wrapping and grouped in storage packs.

INTENDED USE

The Sistema de Implante Nacional Dental Implant System is intended to be surgically placed, either immediately or delayed, in the bone of the maxillary and/or mandibular arch to provide support for crowns, bridges or overdentures. Restorations supported by two or more Sistema de Implante Nacional implants may be loaded immediately after implant placement if primary implant stability has been achieved.

DEVICE DESCRIPTION

Sistema de Implante Nacional Dental Implants are threaded, tapered and straight endosseous dental implants made of commercially pure titanium and intended for use with Sistema de Implante Nacional System abutments and instruments. The implants are offered in a multiple of lengths and diameters. They are offered with a machined surface or acid etched.

EQUIVALENCE TO MARKETED PRODUCT

The Sistema de Implante Nacional Dental Implant System is substantially equivalent, for the purposes of FDA's regulation of medical devices, to Class II medical devices that are cleared for marketing in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2009

Sin Sistema De Implante Nacional LTDA
C/O Mr. Floyd G. Larson
President
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K051859
Trade/Device Name: Sistema de Implante Nacional Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: July 6, 2005
Received: July 8, 2005

Dear Mr. Larson:

This letter corrects our substantially equivalent letter of September 23, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

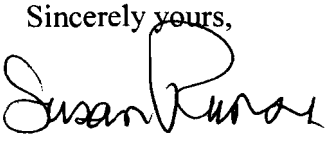
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K051859

Device Name: Sistema de Implante Nacional Dental Implant System

Indications for Use:

The Sistema de Implante Nacional Dental Implant System is intended to be surgically placed in the bone of the maxillary and/or mandibular arch to provide support for crowns, bridges or overdentures. Implants may be placed immediately after tooth extraction or following bone healing. Restorations supported by two or more Sistema de Implante Nacional implants may be loaded immediately after implant placement if primary implant stability has been achieved.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kim Mealey for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K051859